Applied Research Process

Clarkson College

Clarkson is dedicated through its mission of preparing student to professionally provide high quality, ethical, and compassionate health care services.

Clarkson College

Prepare to be the **best.**

Mission

Preparing students to professionally provide high quality, ethical and compassionate health care services.

Values

LEARNING

The lifelong process of education through both structured and unstructured experiences.

CARING

An empowering relationship through an attitude of empathy, compassion and respect for those with whom we interact and serve.

COMMITMENT

Dedication to the shared mission of Clarkson College.

INTEGRITY

Adherence to moral and ethical standards in personal, professional and organizational actions.

EXCELLENCE

A level of performance in which all individuals strive for extraordinary quality.

Clarkson College

Prepare to be the **best.**

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Executive Summary

This document is intended to clarify and emphasize the expectations and process flow of research at Clarkson College for students, internal and external constituents. The Mission of Clarkson College is to prepare students to professionally provide high quality, ethical and compassionate health care services. Through the Values of the College: Learning, Caring, Commitment, Integrity and Excellence, the College remains student centered and is focused on the delivery of extraordinary education.

The applied research at Clarkson College is defined on page 5 of this document and reflects the student learning outcomes of communication, critical thinking, technology, diversity and professional behavior. The applied research process includes all undergraduate, master's and doctoral academic programs, faculty/staff and external constituents. The process requires continuous assessment and reporting. The outcomes of this process, coupled with the academic program assessment, are used to make recommendations for improvements annually.

Questions regarding the flow and information in this manual can best be answered through consultation with your advisor or program director. External constituents may contact the Center for Teaching Excellence.

Applied Research Overview

Clarkson College Applied Research Definition:

The following definition was chosen by the College which reflects both the Mission of the College and the Clarkson College five Student Learning Outcomes; Communication, Critical Thinking, Technology, Diversity and Professional Behavior.

> *Clarkson College Applied Research focuses on the practical scholarship of integration and application.* ***Professional*** *practice benefits from the translation of original research to the* ***global society,*** *bringing life theory and reality to research. Scholarship is demonstrated through a research project that reflects the breadth of the student's education and that synthesizes the knowledge gained through their course of study. Students will use* ***critical thinking*** *skills to propose an evidence-based strategy, implement an intervention, and/or evaluate outcomes. The project may take on many forms. However, the common elements are translation of evidence to improve practice, processes and/or outcomes related to the research question, and to* ***communicate*** *their findings using appropriate* ***technology****.*

Leveling of Research at Clarkson College
Research concepts are introduced to our students in all degree levels:

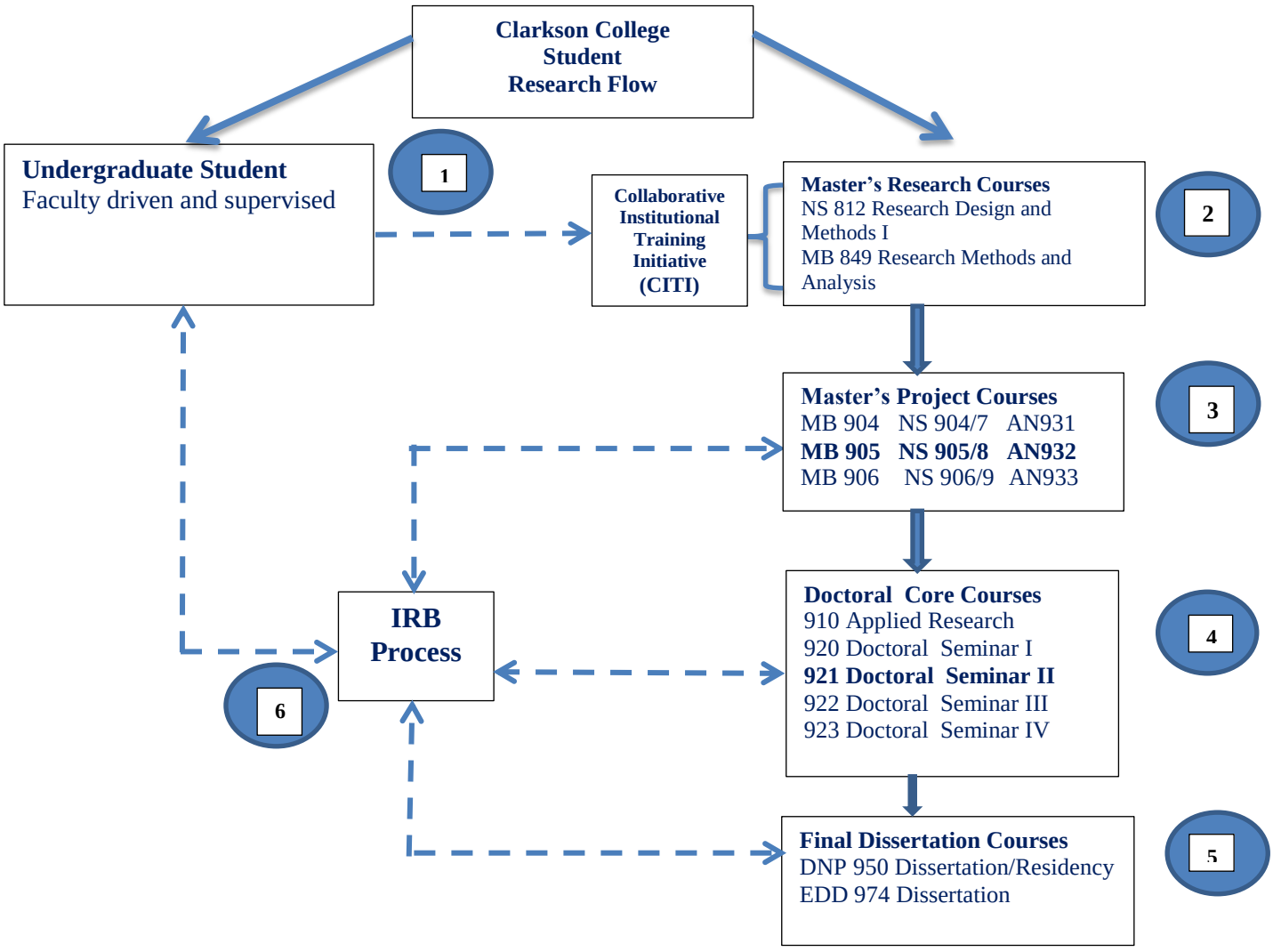
The **Undergraduate Level** (Appendix A) provides a basic knowledge of research design and elements of the research process. Students are introduced to statistics, literature review, and appraisal of published articles. Students are expected to create analytical papers supported and/or substantiated with scholarly sources. A variety of assignments and projects are used to assess student learning throughout the undergraduate programs.

The **Masters Level** (Appendix B) provides the students an in-depth knowledge of the research process. Various research designs are analyzed in addition to exploring the relationship between research, theory and practice. The courses will prepare the student to appraise published research studies and apply research findings to guide evidence-based practice. Students are expected to integrate and synthesize knowledge, strategies, theories and principles learned throughout the course of study, bridging the gap between coursework and professional practice through to completion of an evidence-based project.

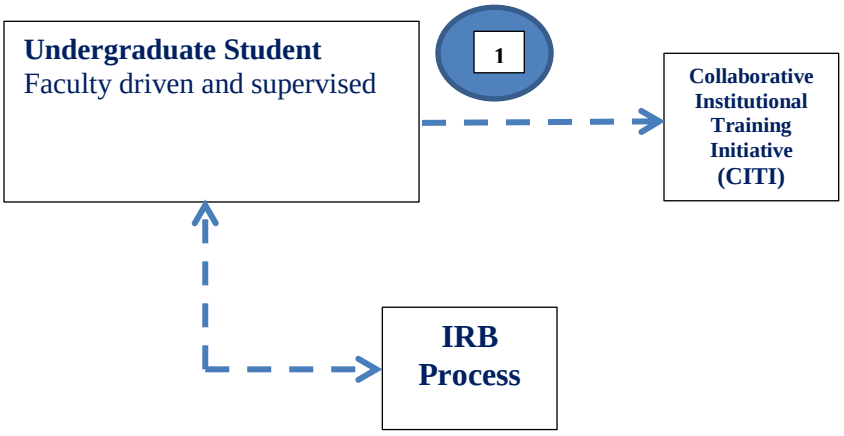
The **Doctoral Level** (Appendix C) provides the students an advanced knowledge of the applied research process. The courses and seminars will prepare the student to evaluate published research studies, design and implement evidence-based research. Students are expected to integrate and synthesize knowledge, strategies, theories and principles learned throughout the course of study culminating in the dissertation.

Applied Research Process - Students

All students follow the Research Process appropriate to their status at the College. The student, faculty/staff and external constituents are depicted in the following processes. In addition, we have developed an Institutional Research Support position that is located in the Center for Teaching Excellence, see student support.



1 - Undergraduate Student



Undergraduate students who wish to conduct research must work with a faculty member with appropriate background and who will serve as primary investigator. The primary investigator (faculty) will be first author and student second on all publications. It is recommended that students have taken a foundational research, scientific investigations or evidence based practice course or can demonstrate they have had the appropriate research components in their discipline. Students must complete the certification in research ethics education, the Collaborative Institutional Training Initiative (CITI).

Components of the research process should include, but not limited to, literature search, article critique, sampling, methodology, review of statistical data, formulation of questions, and application to practice in their major discipline.

A variety of undergraduate courses within each discipline and General Education provide students with foundational knowledge of the research process (Appendix A).

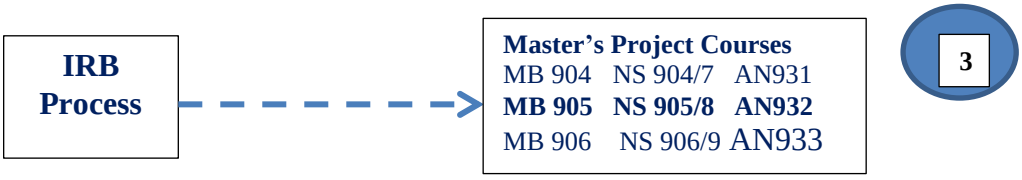
2 – Graduate Research Courses

For master's level students, either NS812 or MB849 or equivalent transfer course must be taken prior to conducting graduate research at Clarkson College.

NS812 & MB849 the master's level research courses cover the entire research process including the following elements:

- Differentiate qualitative, quantitative, and mixed-methods research.
- Ensure complete/current certification in research ethics education.
- Define research question
- Literature review
- Theoretical framework
- Design methodology
- Data collection procedure
- Data analysis
- Conclusions, implications and need for future research

3 – Master's Project Courses



1. **Master's in Health Care Administration:**

Effective fall 2012 the courses in the MHA are as follows:
MB904: Problem statement, literature review
MB905: IRB approval; methodology/sampling; environmental scanning/ data; and other business plan components
MB906: Completion and finalization of business plan

Outcome: Business Plan

2. **Master of Science in Nursing:**

Effective fall 2011 the courses NS 904, NS905, and NS906 transitioned to NS907, NS908, NS909 to implement evidence-based projects.
NS 907: Problem statement; Theoretical framework; literature review
NS 908: IRB approval, methodology; query letter
NS 909: Data collection/analysis; findings and discussion; dissemination of data collected

Outcome (NS904-NS906): process, clinical guide, tool, or business plan
Outcome (NS907-NS909): article for publication

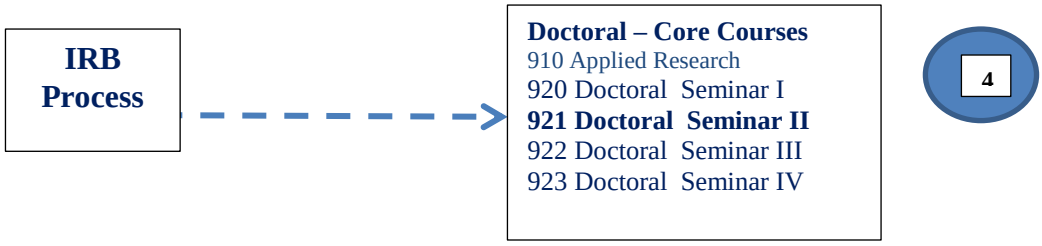
3. **Master of Science in Nursing: Major - Nurse Anesthesia**

Nurse Anesthesia Senior Projects
AN 931 Senior Project I: Problem statement, proposed needed change, theoretical framework, literature review
AN 932 : IRB approval, methodology, data collection
AN 933: Implementation/presentation

Outcome: Implementation/presentation and or publication

Note:
a. On all published master's projects, the student will be first author and the master's project advisor will be second author.
b. It is the advisor's responsibility to ensure the IRB process is closed at the completion of the project.

4 – Doctoral Core Courses



1. Doctoral Research Core Course

Admission to the Doctoral programs requires a graduate level statistics course and a graduate level research course. The first research course at the Doctoral level is DNP /EDD 910 Applied Research. This course provides knowledge and skills for understanding, analyzing, and designing research at the doctoral level. Students explore the application of research to the practice setting. Qualitative, quantitative and mixed methods research designs are analyzed. Ethical and social change implications of conducting research, producing knowledge, and engaging in scholarship are emphasized. Students will synthesize and apply their knowledge and skills of applied research.

2. Doctoral Seminar Courses

DNP/EDD 920 Doc Seminar I: Course focuses on the dissertation process and a thorough review of the literature surrounding the student's proposed topic. The Coordinator of the Doctoral Seminar courses will determine the student/chair match based on research expertise and availability. The roles of the committee chair and committee members are discussed as well as College resources.

Outcome: Selection of research topic, literature review, dissertation process and chair/member selection.

Note:

a. Responsibility of Committee Chair: Oversee Doctoral student's research process. Students will communicate directly with the Chair of their committee.

- Determine process schedule for student completion
- Dissemination of student dissertation drafts from the committee members
- Synthesize feedback from committee members
- Reserves the right to make final decisions on dissertation content.
- Bring student progress, questions and updates to Research Forum
- Schedules final defense
- Finalize IRB process with dissertation completion

b. Responsibility of Committee Members: Read, critique and give feedback to Chair per the established process schedule. All committee members and chair will sign off on the final dissertation.

DNP/EDD 921 Doc Seminar II: This course focuses on scientific inquiry and emphasizes the formulation and writing of a dissertation/research project proposal and the process for IRB.

Outcome:

a. Comprehensive portfolio over Core curriculum; see Doctoral Handbook
b. Completion of methodology, dissertation proposal to committee for approval, and IRB submission.

Note:
The IRB is responsible for the review of all research performed at Clarkson College in order to ensure that professional, ethical and legal standards concerning the use of human participants are being followed. The Standards are those in the Title 45 Code of Federal Regulations, Part 46: Protection of Human Participants (45 CFR Part 46). The IRB will meet on a monthly basis.

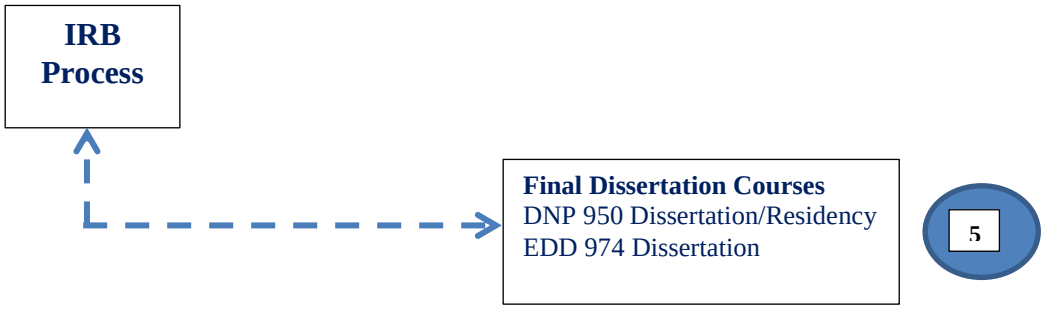
DNP/EDD 922 Doc Seminar III: This course focuses on the doctoral proposal, data collection, data analysis, and formulation of dissertation/research project outcome chapters. A thorough discussion of the review of literature refuting or supporting the dissertation/research project is highlighted.

Outcome: data collection, analysis and results

DNP/EDD 923 Doc Seminar IV: This course focuses on the completion of the dissertation/research project. Content and format issues and recommendations for further research are discussed. Dissemination of the project outcome and possible outlets for publication are covered.

Outcome: Continued dissertation draft and possible publications.

5 – Final Dissertation Courses



DNP 950 Residency/Dissertation: This course applies knowledge and skills to improve healthcare outcomes, while providing learners with the opportunity to participate in a residency in their area of specialization.

Outcome: Completed dissertation

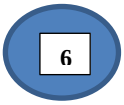
EDD 974 Dissertation: An integrated practicum or practice immersion experience that generates a final scholarly project (dissertation).

Outcome: Completed dissertation

Note:

a. On all published dissertations the student will be first author and the chair will be second author.
b. Acknowledgement on publications of committee members is encouraged within one year of graduation.
c. It is the chair's responsibility to ensure the IRB process is closed.

6 – IRB Process



IRB Process

"Investigators must balance their interest in gathering data and answering research questions with society's mandate to protect the rights and safeguard the welfare of research participants. Society has granted a conditional privilege to perform research on human beings…the condition is that it must b conducted in a way that puts the rights and welfare of human participants first" (Gottesman, 2004, p.i).

The Committee reviews and updates Clarkson College IRB process and forms incorporating University of Nebraska Medical Center (UNMC), The Nebraska Medical Center (TNMC), Clarkson College, The Department of Health and Human Services (HHS), and the Office of Human Subjects (HRP) requirements. The IRB maintains certification with Federal Wide Assurance (FWA) and Office of Human Research Protection OHRP.

The Institutional Review Board (IRB) at Clarkson College was established during the 2003/2004 academic year. The IRB is a committee composed of at least five members from a variety of disciplines with experience and preparation in research. Included are members from and community. The committee meets on a monthly basis to review submitted applications for research. The members determine the viability of proposed research in accordance with institutional standards, professional practice, and applicable law. At least one member's primary concern is scientific, one is non-scientific, and one is not affiliated with Clarkson College. The IRB reserves the right to consult with other experts when a research proposal is beyond the scope of the expertise of the current board members.

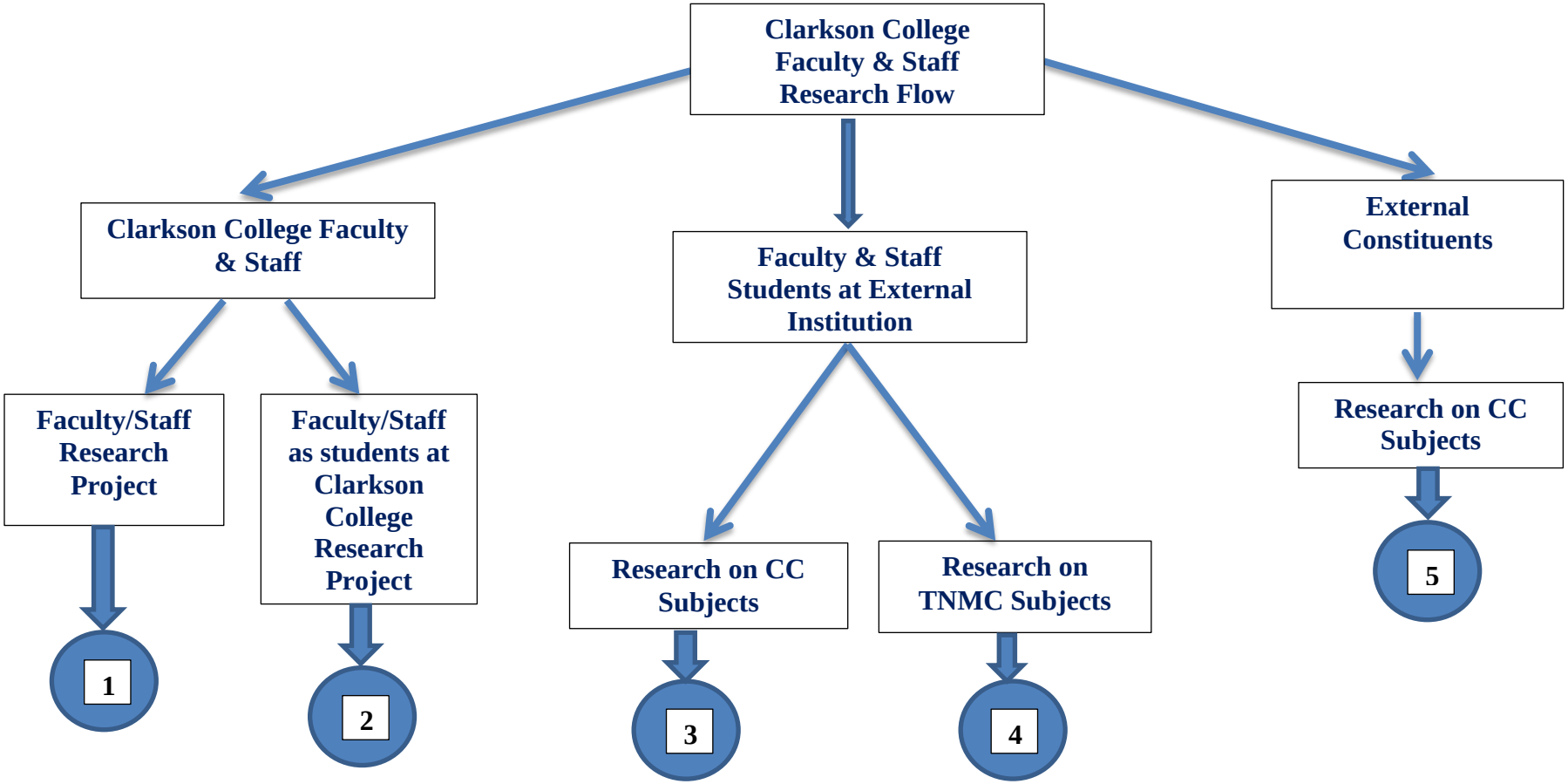
The IRB is responsible for the review of all research performed at Clarkson College in order to ensure that professional, ethical and legal standards concerning the use of human participants are being followed. The Standards are those in the Title 45 Code of Federal Regulations, Part 46: Protection of Human Participants (45 CFR Part 46). The IRB shall determine that risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. In addition, risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that my reasonably be expected to result (46.111). Privacy, confidentiality must be protected, and data must be monitored to ensure subject safety. Additional safeguards must be provided for vulnerable populations.

> *The Clarkson College Institutional Board will not approve research that is deemed more than minimal risk to participants and will not approve research involving animals.*

IRB Process Manual – **Appendix D**

Applied Research: Faculty, Staff & External Constituents

The College does not require their faculty to research or publish as part of their contract; however the Applied Research Process appropriate to their status at the College as a faculty or staff member follows the process below. The faculty, staff and external constituents are depicted in the following processes and the details in each step of the flow are outlined in detail in the table below. The Institutional Research Support functions are under (IRS) heading.



Research Process – Clarkson College Faculty & Staff		
Level	**Content**	**IRS**
Clarkson College Faculty & Staff **1- Faculty/Staff Research Project**	**Research Project Process –**Notify Director/Manager of intent for research - If faculty/staff does not have a Master's degree or above contact IRS for a Mentor listing - Complete CITI/NIH or provide current documentation of completion (3years); send copy to Director/Manager and IRS for tracking - Develop Research Proposal: Define research question, Literature review, Methodology, Proposed analysis - Apply to IRB to obtain approval - Notify IRS for potential research resource needs (statistics, reader, writing) - Submit Dr. Pat Perry Academic Project application if appropriate - Complete Research - Disseminate outcomes and communicate to appropriate venue (Department, Operations Council, Senate, Community) - Notify IRB and IRS of completion for tracking purposes	Online link to CITI training Track CITI/NIH student certificates Business Plan template Location of resources for APA, statistics and writing Monitor IRB process for faculty and staff
2 - Faculty/Staff as Students at Clarkson College Research Project	Faculty and Staff who are Clarkson College students will follow the Research Process of Clarkson College Students	
Faculty & Staff who are Students at an External Institution **3 - CC subjects** **4 – TNMC subjects**	**3 - Subject matter – Clarkson College Faculty, Staff or Students** - Seek IRB approval from your resident institution – complete application to conduct research at Clarkson College and obtain approval letter - Submit application and approval letter to Clarkson College IRB for approval **4 - Subject matter – TNMC Employees or Patients** - Individuals must collaborate with TNMC Office of Research and Evidence Based Practice and UNMC IRB	Track IRB submissions
External Constituents **5 - CC subjects**	**5 - Subject matter – Clarkson College Faculty, Staff or Student** - Contact is IRS for application to conduct research at Clarkson College - Submit to Clarkson College IRB for approval.	Track IRB submissions

Applied Research Forum

A Research Forum has been established by the College and is facilitated by the VPAA with supported by the Coordinator, Institutional Research Support. Advisors and Chairs in the graduate and doctoral programs are required to attend and bring forth their students' research elements. Other faculty, staff and appropriate students are welcome to attend.

Standing Agenda
An agenda has been established by the VPAA and will be conducted on a monthly basis. The following agenda is followed to address research issues and to help faculty and students understand the elements of applied research at Clarkson College.

Agenda Structure

1. **Presentation of projects:** undergraduate, graduate and doctoral projects. Faculty, staff and external constituent applications are presented.

2. **Discussion of Research Questions:** intended to assist the advisor/chair in determining any issues and potential methodology.

3. **Methodology Issues:** issues regarding sampling, methodology and protection of human subjects must be addressed and discussed prior to IRB submission.

4. **Issues/Concerns:** additional issues to be discussed

5. **Applied Research Education:** presentations will include components of the applied research process.

College Support Services

The Center for Teaching Excellence (CTE)
The Center supports teaching and learning at Clarkson College. The Center brings together a diverse assembly of resources for faculty and administration to aid in the continued pursuit of efficient and effective student learning. CTE houses specialists in faculty development, educational technology, instructional design, community relations, institutional effectiveness, testing services, disability accommodations, clinical contracting and preceptor agreements, and a newly appointed position of Coordinator, Institutional Research Support.

Coordinator, Institutional Research Support
This individual will assist all faculty, students, and staff as they work through the research process at Clarkson. The primary function of this role is the creation and maintenance of an online research site complete with examples of forms, documents, process and resources necessary in the research process. Tracking of the students' progress and assisting with additional resources is another aspect of this role. This person coordinates the institutional research processes and supports the faculty and student's needs. The functions include, but are not limited to, maintaining the research web page for student resources, track CITI training certificates for students and faculty, resource coordinator for statistics and writing, and monitor the IRB process for students.

Library Resources:
The Library offers all resources to the online students through Pearson/eCollege or the Clarkson College Website. The Library's present trend to utilize technologies to support student access to information resources is possible through full-text databases, EBSCO's A to Z tool, electronic books, and instructional materials available on the college's Online Campus course management system. The Library collection includes 150 current journals, 408 audiovisuals, 3302 books, and more than 20 databases. In addition, students may access full text from 10,721 unique journal titles using A to Z.

The library collection is evaluated continually by the library staff, and additional purchases are added to support college programs and curriculum changes. Recommendations from faculty and students and purchasing information from other medical libraries serve as the basis for collection purchasing decisions.

The Library is an active member of ICON, a Nebraska and Western Iowa consortium of health science libraries. ICON member libraries support the sharing of information and expertise through quarterly meetings and participation in free interlibrary lending. The library participates in the Nebraska Academic Libraries Reciprocal Borrowing Agreement that gives faculty and students access to academic libraries in Nebraska. Access to library collections throughout the United States is offered via DOCLINE and OCLC.

APPENDIX A:

Undergraduate Research Assignments: Sampling
March 2012

Course Number /Title	Research Assignment	Evaluation Methods any tie to Program Outcomes	Level and Program
General Education			
HC 104 Core I	Research Paper or Service Presentation.	Students have option of completing 20 hours of community service and do a presentation or complete a Research Paper	General Education
HC 204 CORE II	Research Paper	Students research the historical aspects of an agency or service site in their area and create a research paper.	General Education
HC 304 CORE III	Service Snapshot	Field Research and citation of statistics and research pertaining to service agencies.	General Education
English 101	Analytical papers supported and/or substantiated with scholarly sources.	Graded paper Course Objective: Use quoted and paraphrased evidence from primary sources in a formal analytical essay	General Education
English 102	Analytical papers supported and/or substantiated with scholarly sources.	Graded paper Course Objective: Use quoted and paraphrased evidence from primary sources in a formal analytical essay	General Education
Statistics 310	Qualitative and quantitative article review, answer research questions, 4 levels of measurement, calculate averages, ability to review data and put it in to various formulas to derive statistical data	2 Major Projects demonstrating use and calculation of various statistical tests, 3 Exams, and weekly home work demonstrating proficiency in statistics.	General Education

Course Number /Title	Research Assignment	Evaluation Methods any tie to Program Outcomes	Level and Program
PY 200 (Health and Human Development)	Research paper	Students read the novel "Infidel" and then discuss one aspect of life span development as presented in the course and utilize supporting research to link the information from the novel to course concepts.	General Education
Undergraduate Nursing			
NS ??	Article Critique	Marsha Cravens class	
NS 350-351	Evidence-Based Practice symposium (review literature, poster presentation, review clinical and national guidelines)	Graded assignment Tied to theory and clinical course competency	Nursing (Bachelor's)
NS 309	Research critiques Final Critique Quizzes with short answers relating to critiquing a research article	Graded assignments Quizzes	Nursing (Bachelor's)
New Nursing Curriculum	Threaded evidence based practice assignment throughout as well as IRB mechanics	Yes	Nursing
RN-BSN	Capstone projects (pick a clinical issue, review of 5 articles and best practice guidelines, develop new nursing intervention)	Graded project individual or group Tied in outcomes and in course competency objectives	Nursing (Bachelor's)
Business/HIM			
BU 121 (Survey of Economics)	Research Paper	Graded Paper with Rubric Course Objective: Apply economic theory to health care issues.	HCBM (Bachelor's)
HM 280 (EHR)	Research Assignment	Students write a brief paper on current EHR topics and current legislative effects on EHRs.	HIT, HIA and HCBM (AS and BS)

Course Number /Title	Research Assignment	Evaluation Methods any tie to Program Outcomes	Level and Program
Business/HIM			
BU 320 (HR)	Training module with an Annotated Bibliography.	Students will create an annotated bibliography to help them research the existing information on a topic. Course Objective: Create a training session using each stage of the systems approach to training.	HCBM (Bachelor's)
HM 342 (Health Care Information Systems)	Discussions/Short Papers	Students utilize at least one outside source to back up ideas and thoughts.	HIT, HIA, and HCBM (Associate and Bachelor's)
BU 470 (Public Health)	Research Paper	Graded Paper with Rubric Course Objective: Evaluate current health policy issues from the perspective of patients, providers, health plans, and the government.	HCBM (bachelors)
HM 475 (Research Methods)	Research Proposal (introduction, problem statement, literature review, study design, data collection, and data analysis). IRB process is also discussed	Students learn about all the various research methods, and choose an HIM topic of their choice and design a research proposal.	HIA (Bachelor's)
Radiologic Technology/Medical Imaging			
RT 250 (Radiation Biology)	Research Articles	Graded assignment with rubric	RT (Associate's)
MI 330 (Pathophysiology)	Research Paper	Graded assignment with rubric Tied to communication outcome	MI (Bachelor's)
Physical Therapist Assistant			
PTA 120 (Therapeutic Modalities I)	Journal Critique	Graded critique with class presentation summary of journal article Course Competency: At the end of this course the student will be able to analyze the professional literature regarding the efficacy of the modalities taught in this course.	PTA (Associate's)

Course Number /Title	Research Assignment	Evaluation Methods any tie to Program Outcomes	Level and Program
Physical Therapists Assistant			
PTA 210 (Therapeutic Modalities II)	Research paper on clinical use of electrical stimulation with research support properly cited	Graded paper Course Competency: At the end of this course the student will be able to critique professional literature related to the clinical efficacy of the therapeutic modalities covered in this course.	PTA (Associate's)
PTA 212 (Professional Issues)	Read scholarly work and answer questions regarding application to practice/pro bono work	Course assignment grade Course Competency: At the end of this course the student will be able to discuss the social responsibility for providing *Pro Bono Publico* services in physical therapy, and under the direction of a physical therapist demonstrate the ability to educate and meet the needs of patients, colleagues, and other healthcare professionals.	PTA (Associate's)
	Cultural sensitivity paper with research support	Graded paper Course Competency: At the end of this course the student will be able to define Service Learning and its application to both the College program and the PT profession as it relates to recognizing individual and cultural differences and how our appropriate responses assist in physical therapy related services.	PTA (Associate's)
PTA 230 Advanced Procedures	Journal Club participation assignment with presentation	Graded presentation and journal critique Course Competency: At the end of this course the student will be able to Differentiate the role of the PT and PTA in patient care and clinical dynamics through a Collaborative PT/PTA student team approach with a focus on case study analysis.	PTA (Associate's)
PTA 240 and 245 (terminal clinical rotations)	In-service presentation supported by literature	Graded clinical project By the end of the clinical rotation the student will prepare and present a formal staff in-service on a topic agreed upon between the clinical instructor and student.	

APPENDIX B: GRADUATE RESEARCH – MASTER'S

Master's Student Requirement: Appraise published research studies and appropriately apply research findings to guide practice.

MHA	MSN
Program Outcomes	**Program Outcomes**
1. Upon completion of the degree requirements for the Master of Science in Health Care Administration, the graduate should be able to: 2. Evaluate strategies based on concepts of leadership and management theory. 3. Convey their thoughts and ideas effectively and assertively. They will demonstrate this in written materials and orally in one-on-one or business presentations. 4. Interpret, synthesize, and apply concepts to evaluate and solve a variety of health care business scenarios, through problem recognition, project management, strategic analysis and integration, and application of quantitative methods to real world business situations. 5. Demonstrate an ability to acknowledge and to recognize those differences that exist among all individuals, such as race, religion, language, values, culture, and other unique characteristics. 6. Maintain the highest ethical, professional, and legal standards of conduct. They will display an ability to work with others, including those with unique qualities or characteristics without compromising integrity. They are willing to accept and respond positively to feedback and constructive critiques. **7.** Demonstrate an appropriate working knowledge of basic computer applications such as Microsoft Word, Excel, and PowerPoint.	Upon completion of the degree requirements for the Master of Science in Nursing , the graduate should be able to: **1.** Design educational strategies to improve culturally appropriate caring practices for clients, families, communities, and populations. **2.** Synthesize complex knowledge of nursing to advocate for holistic client centered care for individuals, families, communities and populations. **3.** Generate policies through teamwork and collaboration in the complex roles of educator, administrator, or advanced clinician. **4.** Construct health care strategies using evidence-based theoretical, scientific, and contemporary knowledge. **5.** Demonstrate leadership skills to improve client health outcomes, facilitate change in health care systems, and appraise ethical-legal dilemmas. **6.** Create systems to promote safety and minimize risks of harm to clients and providers. **7.** Use information technology to interpret data, communicate, and evaluate decision making. **8.** Advocate for professional behaviors that advance the profession and improve health care.
End Product: Capstone Project	**End Product: Journal Article and Poster Presentation**

MB 849 Research and Analysis (3 hrs) Required	NS 812 Graduate Research (3 hrs) Required
The research process is examined in detail. Various research designs, both quantitative and qualitative, are analyzed in addition to exploring the relationship between research and practice. Furthermore, the course will prepare the student to critique published research studies, both qualitative and quantitative, and to apply research findings appropriately to practice.	This course is an entry graduate level course exploring the foundations of nursing research through an evidence-based approach for integration and utilization within the advanced nursing practice environment. The research process is examined in detail. Various research designs, both quantitative and qualitative, are analyzed in addition to exploring the relationship between research, theory and practice. The course will prepare the student to appraise published research studies, both qualitative and quantitative, and appropriately apply research findings to guide evidence-based practice
Course Objectives: Upon completion of this course, the student should be able to: 1. Recognize the differences between applied and basic research and the use of the business research/plan in the development and implementation of strategy. 2. Define concepts associated with the research process such as proposition, variable, hypothesis etc., and discuss how theories are generated. 3. Explain the various quantitative research designs, including experiment, quasi experiment, and non-experimental. 4. Explain a variety of qualitative research methods, including phenomenology, grounded theory, ethnography, and case study. 5. Describe the role of ethics in research, including defining the rights and obligations of researcher and research participant, and the Institutional Review Board (IRB) process. 6. Explain concepts associated with sampling and fieldwork including the importance of sample, target population, probability and non-probability samples, and the process of interview construction and application. 7. Discuss measurement and scaling concepts and the process of questionnaire design. 8. Explain different data collection and data analysis methods used in quantitative and qualitative research inquiry. 9. Critically appraise the research process, including the reliability and	Course Objectives: 1. Identify the components of the research process (e.g. problem statement, purposes, literature review; theoretical or conceptual framework, variables, protection of human participants, sampling, measurement and data collection procedures, data analysis, implications and conclusions) that are appropriate for the various types of qualitative and quantitative research approaches. 2. Critically appraise published quantitative and qualitative nursing and health care related research studies to determine the success and limitations of the study in addressing the problem and/or purpose(s) identified. 3. Acquire new knowledge by reviewing evidence-based findings for the purpose of directing and improving nursing practice, analyzing health care interventions and outcomes, and to initiate change. 4. Critique research instruments (e.g. tools, measures) for validity and reliability issues. 5. Appraise quantitative and qualitative studies to determine evidence base strength. 6. Appraise statistical analysis conducted and appropriateness of findings reported for each research hypothesis/purpose/question. 7. Access current and relevant data needed to answer researchable questions identified in one's nursing practice. 8. Utilize information systems to initiate a line of inquiry into

validity of findings, as utilized and presented in selected published quantitative and qualitative research reports. 10. Prepare a literature review that addresses a research topic from the AHRQ list of vulnerable populations and includes the analysis and synthesis of critically appraised research.	comprehensive databases consistent with reviewing, retrieving, and storing data consistent with the research process. 9. Write and communicate effectively—identifying a nursing problem, demonstrate an understanding of the research evidence related to this problem, critically analyzing the problem, and current knowledge, write a PICO/PICOT question, and developing a research strategy for a researchable problem. 10. Complete assignments using correct research and statistical terminology along with adherence to scholarly presentations established by the APA format style.
Evaluation: **Personal Goals Statement** Research topic Bibliography Problem Statement Exercises 1st draft of lit review (3 published research reports) CITI completion Discussions/critiques Qualitative coding exercise Quizzes Final Paper (lit review of total of 6 published research reports) Revisit Personal Goals Statement	Evaluation: Syllabus & Course Quiz (P/np Nursing Policy – Procedure Scenario for PICO Development Research Question Templates Nursing Research Problem Statement Discussion and PICO/PICOT question Quantitative Research Proposal 1 Submission of On-Line Portfolio Quantitative Research Proposal 2 Protection of research participants training. Complete the CITI training. Qualitative Discussion Dissemination of research results Open Forum Discussion Board

MB 900 Capstone (3 hrs) **Required**	**NS 907, 908, 909 Evidence Based Practice Project (3hrs total)** **Required**
The capstone experience is the culmination of the learning experiences in the Master of Health Care Administration program. There are two main components to the capstone: a comprehensive examination designed to evaluate the student's mastery of the field of health care administration and a capstone project. Through critical thinking, students are expected to integrate and synthesize knowledge, strategies, theories and principles learned throughout the course of study. Both the exam and project will bridge the gap between coursework and professional practice.	These three courses demonstrate the culmination of previous learning experiences into a scholarly, evidence based practice journal article and poster presentation. The EBP research project allows students to investigate a question of practical importance, or investigate a nursing problem of practice importance by developing and testing an intervention, curriculum, or protocol for application within a specific setting.
Course Objectives: Students who successfully complete this course will be able to: 1. Demonstrate a professional level of competence in health care leadership, communications, information systems, finance, strategic management, and law. 2. Apply principles studied in the Health Care Business Leadership program to a business problem or organizational opportunity. 3. Research and demonstrate understanding of a health care problem. 4. Produce a scholarly written report that demonstrates the ability to investigate, develop, and synthesize data. 5. Verbally present data, in a business setting, using professional public speaking techniques and equipment.	Course Objectives: NS 907: Each student will complete a problem statement, theoretical framework, and compile a literature review to include the concepts of QSEN, IOM, *Healthy People 2020*, gerontology, and/or genetics and genomics as appropriate, according to established requirements relevant to their area of concentration. NS 908: The student will build on the material completed in NS 907 I and will add the methodology, IRB components, and journal query letter. NS 909: The student will build on the material completed in NS 907 I and NS 908 II and will complete the project to include data collection and analysis, findings, discussion, implications and or recommendations. A completed journal article and poster presentation is required.
Evaluation (Graded): Project Proposal Discussion Exam Thesis/Business Plan Oral Power point Presentation	Evaluation (Pass/Fail): Complete EBP Project including PICOT (research questions), Literature review, Theoretical Framework, Methodology (Research Design, Instruments, Analysis plans), Ethical Legal implications, IRB application, Data collection, Analysis, Findings, Conclusions & Recommendations. Write Article and submit to Journal. Presentation with Poster.

APPENDIX C: GRADUATE RESEARCH - DOCTORAL

Doctoral Applied Research

DNP	Ed.D.
Program Outcomes	**Program Outcomes**
Graduates of the DNP will have expanded knowledge and expertise required of advance practice nurses to provide leadership through collaborative an innovative decision-making in an evidence-based practice environment. Graduates will demonstrate excellence in interdisciplinary, client-centered communication, translation of research, and implementation of evidence-based change to promote quality health care outcomes. Graduates will have a working knowledge of the processes involved in the development of state, national an professional policies governing health care. Graduates of the DNP Program will: 1. Integrate advanced communication skills/processes that lead to caring practices improving the healthcare delivery for systems, diverse organizational cultures and populations including clients and providers. 2. Implement change in healthcare delivery systems through consultative and leadership skills with intra-professional teams, consumers and other stakeholders. 3. Synthesize principles of business, finance, economics and health policy quality improvement methodologies to develop and implement effective plans for practice-level and/or system-wide practice initiatives that will improve quality of care delivery. 4. Measure an dimporove accountability for quality health care and safety for populations and other professionals. 5. Influence healthcare policy and practice to achieve excellence in healthcare.	Graduates from the Ed.D. program will have expanded knowledge and expertise required to provide healthcare leadership in both academic and administrative roles. Graduates will demonstrate excellence in interdisciplinary communication, translational research, and problem-solving, while providing quality health sciences education. Their major course work will supply a foundation in outcomes assessment, learner development, transformational leadership and brain-linked research which strengthens their ability to implement innovative educational approaches. Graduates will have the skill set needed to assess, design, implement and evaluate a process or program utilizing change theory, conflict management and adult educational principles. Graduates of the Ed.D. Program will: 1. Create educational leadership strategies to meet the needs of diverse learners. 2. Engage in interdisciplinary communication, analysis and problem solving that reflects evidence-based practice. 3. Implement assessment and evaluation strategies using information technology to improve learning, productivity and professional practice. 4. Synthesize knowledge of educational and leadership theory, management skills, leadership strategies and data to transform organizations and educational institutions. 5. Integrate ethical, legal and professional principles into decision making in the educational leadership setting.
End Product: Dissertation/Residency	**End Product: Dissertation**

Course Description, Objectives, and Evaluation	Course Description, Objectives, and Evaluation
DNP/EDD 910 Applied Research (3hr)	**DNP/EDD 910 Applied Research (3hr)**

Course Description This course in advanced research provides students with knowledge and skills for understanding, analyzing, and designing research at the doctoral level. Students explore the application of research to the practice setting. Quantitative, qualitative, and mixed-method research designs and methods are analyzed. Ethical and social change implications of conducting research, producing knowledge, and engaging in scholarship are emphasized. Students will synthesize and apply their knowledge and skills of applied research.	Same for all doctoral students
Course Objectives: This course prepares the student to: 1. Differentiate between the components of the research process for the various design methodologies. 2. Analyze theoretical frameworks relevant to applied research within a practice setting. 3. Demonstrate ethical/legal values in conducting research. 4. Construct a study using a quantitative, qualitative, or mixed-method research design.	Course Objectives Same
Evaluation: To be determined by instructor	Evaluation Same
DNP/EDD 920 Doctoral Seminar I (1hr)	**DNP/EDD 920 Doctoral Seminar I (1hr)**
Course Description This course focuses on the dissertation process and a thorough review of the literature surrounding the student's proposed topic. The students' committee chair and members will be identified. The roles of the committee chair and committee members are discussed, as well as College resources.	Same for all doctoral students
Course Objectives: This course prepares the student to: 1. Differentiate the roles, expertise and expectations of the doctoral committee. 2. Use informatics to explore College resources available to the student.	Course Objectives: Same

3. Formulate an applied research dissertation topic. 4. Conduct a preliminary review of literature related to the selected topic. 5. Present topic and supportive literature to chair and committee for discussion and approval.	
Evaluation: To be determined by instructor	Evaluation: Same
DNP/EDD 921 Doctoral Seminar II (1hr)	**DNP/EDD 921 Doctoral Seminar II (1hr)**
Course Description This course, focusing on scientific inquiry, emphasizes the formulation and the writing of a dissertation/research project proposal and the process for IRB. Methodology and content for each of the proposed chapters are defined. **Note:** The Comprehensive Assessment of Core (Comps) is not a credit course. However, it must be completed with a passing mark in Doctoral Seminar II.	Same for all doctoral students
Course Objectives: This course prepares the student to: 1. Design the methodology and the appropriate application of the theoretical framework for the dissertation proposal. 2. Develop and gain approval of proposal from dissertation committee. 3. Present completed IRB application to dissertation and IRB committees for approval.	Course Objectives: Same
Evaluation: TBD by instructor	Evaluation: Same
DNP/EDD 922 Doctoral Seminar III (1hr)	**DNP/EDD 922 Doctoral Seminar III (1hr)**
Course Description This course focuses on the doctoral proposal, data collection, data analysis and formulation of dissertation/research project outcome chapter(s). A thorough discussion of the review of literature refuting or supporting the dissertation/research project topic is highlighted.	Same, this is a Core Course for the doctoral students
Course Objectives: This course prepares the student to: 1. Generate findings based on data collection and analysis.	Course Objectives: Same

2. Analyze the literature to support or refute the research results. 3. Develop remaining chapters of the dissertation	
Evaluation: To be determined by instructor	Evaluation: Same
DNP/EDD 923 Doctoral Seminar IV (1hr)	**DNP/EDD 923 Doctoral Seminar IV (1hr)**
Course Description This course focuses on the completion of the dissertation/research project. Content and format issues, and recommendations for further research, are discussed. Dissemination of the project outcome and possible outlets for publication are covered.	Same for all doctoral students
Course Objectives: This course prepares the student to: 1. Defend the dissertation to the candidate's committee for final approval. 2. Identify possible refereed publication venues for the candidate's dissertation. 3. Prepare a manuscript for an identified refereed journal following the dissertation committee's approval.	Course Objectives: Same
Evaluation: To be determined by instructor	Evaluation: To be determined by instructor
DNP 950 Residency/Dissertation (3 credit hours/135 clinical hours)	**EDD 974 Dissertation (3hrs)**
This course applies knowledge and skill to improve healthcare outcomes, while providing the students with the opportunity to participate in a residency in their area of specialization. The students gain competence analyzing organizational systems and facilitating change in healthcare delivery. The students will have opportunities to evaluate current practice, translate research into practice and participate in activities aimed at improving the access, efficiency and quality of healthcare systems. Residency activities provide the students with opportunities to participate in professional service activities to expand their area of research or clinical interest and/or develop significant scholarly pursuits. The focus is on creating change in the healthcare system through analysis, synthesis, critique, and application of evidence-based practice to support accessible high quality, safe, efficient, and effective healthcare. Clinical sites for the	This course culminates in the final dissertation as demonstrated through research that reflects the breadth of the student's education, synthesis of the knowledge gained, and the translation of evidence to improve practice. The dissertation will be defended in an open forum to an inter-professional committee.

DNP Residency may include collaboration with experts in community, local, state, and national healthcare agencies. Residency activities are selected by the student under the guidance of the faculty advisor and preceptor.	
Course Objectives: This course prepares the student to: 1. Analyze emerging clinical patterns and problems within a practice setting, healthcare organization, community, or system. 2. Assess the access, efficiency, and quality of healthcare systems within diverse organizational cultures and populations. 3. Evaluate the effectiveness of evidence-based clinical practice models that improve patient safety and health outcomes. 4. Employ consultative and leadership skills with intra-professional and inter-professional teams to create a desired change. 5. Design an evidence-based clinical practice strategy that meets current and future needs based on scientific findings in nursing, organizational, political, economic, and/or other related sciences. 6. Implement the student designed evidence-based clinical practice strategy in a healthcare-related environment.	Course Objectives: This course prepares the student to: 1. Analyze emerging research and apply the findings from the problem statements. 2. Evaluate the effectiveness of evidence-based health care education models that improve patient safety and health outcomes. 3. Integrate educational theories into leadership roles to enhance or create a desired change. 4. Implement the student designed evidence-based educational strategy in a healthcare-related environment.
Evaluation: Pass/No Pass	Evaluation: Pass/No Pass
Note: Students may not have a complete dissertation at the end of the doctoral seminars and dissertation course. In this case, students my continue to take up to 8 credit hours to finish their dissertation. There is a maximum of 5 years to complete the DNP or Ed.D.program. **DNP 999/EDD 999 Dissertation Completion (1-8 hrs.)** This course includes guided study in dissertation completion under the upervision of the Committee Chair. Independent Study Form is required before registration. Approval by Committee Chair is required. Pass/No Pass	

APPENDIX D: INSTITUTIONAL REVIEW BOARD MANUAL

CLARKSON COLLEGE INSTITUTIONAL REVIEW BOARD
APPLICATION GUIDEBOOK

This manual is intended as a guide to implement Clarkson College Policy OG-8: Institutional Review of Research Involving Human Subjects Policy
Updates will be posted online.
For any questions, please contact
Dr. Linda E. Jensen
402-552-6093
irb@clarksoncollege.edu

ACKNOWLEDGEMENTS

Clarkson College thanks our colleagues at College of Saint Mary and the University of Nebraska Medical Center for use of their IRB materials to assist in the design of our handbook.

SECTION 1: OVERVIEW OF INSTITUTIONAL REVIEW BOARD AT CLARKSON COLLEGE

"Investigators must balance their interest in gathering data and answering research questions with society's mandate to protect the rights and safeguard the welfare of research participants. Society has granted a conditional privilege to perform research on human beings…the condition is that it must be conducted in a way that puts the rights and welfare of human participants first" (Gottesman, 2004, p. i).

Clarkson College created its Institutional Review Board (IRB) during the 2003-2004 academic years. The IRB is composed of at least five members from a variety of disciplines with experience and preparation in research as well as community members. The members determine the viability of proposed research in accordance with institutional standards, professional practice, and applicable law. At least one member's primary concern is scientific, one is non-scientific, and one is not affiliated with Clarkson College. The IRB reserves the right to consult with other experts when a research proposal is beyond the scope of the expertise of the current board members.

IRB Responsibilities

The IRB is responsible for the review of all research performed at Clarkson College in order to ensure that professional, ethical, and legal standards concerning the use of human participants are being followed. The Standards are those in Title 45 Code of Federal Regulations, Part 46: Protection of Human Participants (45 CFR Part 46) and include the ethical principles of The Belmont Report. In order to approve research covered by this policy, the IRB shall determine that risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. In addition, risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (46.111). Privacy and confidentiality must be protected, and data must be monitored to ensure subject safety. Additional safeguards must be provided for vulnerable populations including .children, pregnant women, veterans of military service, prisoners, and individuals who are decisionally impaired such as developmentally delayed or psychiatric patients.

The Clarkson College Institutional Review Board will not approve research that is deemed more than minimal risk to participants and will not approve any research involving animals.

Research involving vulnerable populations must have Full Board Review.
Clarkson IRB meetings will be held monthly for applications that require **Full Board Review**.
The Clarkson College IRB Committee will attempt to review **Expedited and Exempt** applications within 2 weeks when classes are in session.
Applications for **Full Review** must be submitted at least one week before regularly scheduled IRB meetings. Meeting dates may be accessed on the Clarkson College Intranet Calendar and will be planned at the beginning of each semester.

SECTION 2: DIRECTIONS FOR CLARKSON COLLEGE IRB APPLICANTS

1. Review the IRB submission deadlines on the Clarkson College Intranet Calendar
Choose a target date and allow yourself plenty of time to complete the process. Submitting early is a good idea in case you have errors that are detected in the preview and review process.

2. Complete your ethics training
Provide a copy of the printout of your CITI ethics certificate. This training may have been completed in a Clarkson College research course. The website is: http://www.citiprogram.org . Record your login information, so that you can return to the site, if needed. There is also process to search for your login if it is not available to you. See CITI TRAINING for more information.

3. Determine the site for your data collection, as that will affect which forms you will complete.

a) If the researcher/student **is employed at The Nebraska Medical Center** (TNMC) and plans to collect data with nurses or patients at TNMC, the faculty/ advisor needs to file a Request for Assistance with the TNMC Office of Nursing Research and Evidence-Based Practice. The purpose of this procedure is to facilitate planning of the TNMC Office so that research and quality improvement efforts can be coordinated with TNMC. The Nurse Researchers (Dr. June Eilers, Dr. Suzanne Nuss, and Dr. Regina Nailon) are very helpful to assist with planning of methodology for research at TNMC and also furnish the Nursing perspective on all UNMC IRB applications. The Request for Assistance is available from _____ and can be e-mailed to Dr. June Eilers at (JEilers@nebraskamed.com). Consult with them as you are planning the logistics of your research methodology.

b) Researchers using The Nebraska Medical Center (employees or patients) should complete the University of Nebraska Medical Center (UNMC) IRB online process for faculty and students to fill out the application forms. This online program automatically formats the application, so it can be printed and easily read by the Clarkson College IRB. It thoroughly addresses the ethical and legal implications of protecting human subjects. It also allows for the students, faculty, and other research team members to work back and forth online on the application. **The form should not be submitted to the UNMC IRB until approved by the Clarkson IRB.** If the research is to be conducted at TNMC, the IRB application will have to be approved by the UNMC IRB **after** approval from the Clarkson IRB is granted. Access http://www.unmc.edu/irb/ for instructions for filling out the UNMC form.

c) The researcher(s) who plans to collect data at other healthcare institution(s) must contact the IRB Committee at the institution where they are collecting data to determine if the healthcare institution requires an alternative IRB application or if the Clarkson College Application can serve for approval consideration. Contact the IRB Chair to determine if the other institution's application can serve as the Clarkson College application.
The researcher needs to be responsible for learning and complying with the procedures required **prior to** data collection at another institution. Final Clarkson College IRB approval will not be granted without assurance from that institution that the study methodology has been reviewed, and permission is granted for data collection.

4. Review all three of the following Level of Determination checklists
Start by reviewing all three checklists beginning on page 13 to determine the level of IRB review that fits your research. If in doubt, always go one level higher. You will need to submit a copy of the appropriate Level of Determination checklist with your application.

5. If you are a student, work with your research advisor to determine when you are ready to develop your IRB application. **A Faculty Advisor or Committee Chair must sign an approval form prior to submission of a student IRB application (pg.**

6. Complete your application using the Clarkson College IRB format beginning on page 21
a. Include all sections of the application. If a section does not apply, do not delete it; mark it N/A.
b. Ask for feedback on your research design. Be sure that it is sound before moving forward.
c. Adhere to all writing conventions in the most recent edition of the APA Style Manual.
d. Include all necessary consent forms—see Consent Form Guidelines and examples in Section 6. Remember to submit consent forms on CLARKSON COLLEGE letterhead
e. Include all data collection instruments (surveys, interview protocols, etc.).
f. A letter of permission from a community site must be submitted before final approval to conduct the research will be granted.

8. Check to see that you have completed components a. through i. below in the following order, in a single document with page numbers.
a. __ Application – APA Style
b. __ References - APA Style
c. __ Level of Determination checklist (appropriate one for your study)
d. __ Consent form(s) on Clarkson College letterhead or request for waiver of informed consent
e. __ Rights of Research Participants form(s) (Section 6)
f. __ Recruitment materials-flyers, email invitations, letters, etc. (Section 7)
g. __ All data collection instruments (surveys, interview protocols, etc.)
h. __ Ethics certificate (See Section 3-CITI training completion)
i. __ Faculty Review and Approval form

9. Forward your completed Application Packet to irb@clarksoncollege.edu on your chosen IRB submission date. Official IRB submission dates are the 1st Monday of each Month

10. Remember that complete and accurate applications that are submitted by an IRB submission deadline will normally be reviewed at the next IRB meeting. If approved, the applicant is issued a letter that includes the research IRB approval number, approval date, and expiration date.

> **Note**: Applications that need corrections or revisions will be returned to the student via official correspondence from the IRB Chair within 7 days, and revisions will be submitted to the Chair.

11. Following Approval, duplicate approved consent form (with assigned IRB Number, approval date and expiration date) and Rights of Research Participants form for distribution to all participants.

12. Note that Extensions and Changes of Protocol may be requested using the *Extension/Protocol Change Request Form* found in Appendix C.

13 When research is complete, submit one-page *Closing the Study Form* (see Section 9) to irb@clarksoncollege.edu within 30 days of completing your study.

14. Research that has been approved by another IRB may be subject to further appropriate review and approval or disapproval by the Clarkson College IRB. Contact IRB Chair regarding appropriate format.

SECTION 3: HUMAN PARTICIPANTS PROTECTION EDUCATION FOR RESEARCH TEAMS ONLINE COURSE

Clarkson College requires all investigators, study personnel, and protocol coordinators engaged in human subjects' research to undergo training in the protection of human subjects. **Each IRB applicant must complete the training and submit an electronic copy of the completion certificate with the IRB application. The training can be accessed through the website listed below.**

1) Go to the CITI website: http://www.citiprogram.org

2) Click on "Register for the CITI Course".
This will take you to another page.

3) Choose the "Participating Institutions" drop down box

4) Select "University of Nebraska Medical Center (UNMC/UNO)"
Click Submit.

5) Create your own User Name and Password using the instructions given.
Type in a Reminder Phrase in case you should happen to forget your password.
Write both your User Name and Password down in a safe place, as you will need this to access the course.
Click Submit.

6) Now you will be taken to a Registration Page. Type in the appropriate information.
***Please note that you only need to type in the information in which there is an * next to it!

7) Now you will be asked a question regarding which group you belong to according to the appropriateness of your research affiliation.

- Select **Group 1** since you are "All UNMC and/or Nebraska Medical Center faculty/students/affiliates/collaborators"

8) Now you will be asked a question regarding whether you have completed the basic course before or not.

- Select **"I have not previously completed an approved Basic Course"** since you are required to complete the Basic Biomedical CITI Course at this time.

9) Your User Name and Password are what you selected. Therefore, you will be able to access the website immediately and begin completing the course. Please access the website at: www.citiprogram.org

Please note the following:

- All UNMC and Nebraska Medical Center faculty/students/affiliates/collaborators must complete the Bio-Medical training.

Follow the directions on the screen to complete the Biomedical Basics Course.

There will be 19 modules, most of which are brief. There are quizzes for most of the modules that you can retake if you do not pass.

*Please be sure to print out a copy of your Course Completion Record when you have completed the Biomedical Basics course (There will be 19 modules) and also save it electronically on a disc. Maintain a copy for your records, and send a copy to Dr. Linda Jensen (jensenlinda@clarksoncollege.edu). It is crucial that the Clarkson IRB Office receives a copy of your Course Completion Record with your IRB application, because the website is not automatically sending these records to us at the current time.

If you are currently enrolled in the MSN Research course or another research course, there may be a dropbox for you to deposit your certificate.

Currently the CITI certification lasts for 3 years. You should plan to have CITI certification during any time you are gathering data in your study.

SECTION 4: LEVEL OF DETERMINATION CHECKLISTS

***Note**: If you determine that your study qualifies for exempt review, complete this checklist and submit a copy with your IRB Application. (Exempt Review means the study must still be reviewed, but not by the full IRB review process). The applicant must request exemption of the research, including the research protocol, from full Board review by submitting the appropriate application and noting at least one or more of the categories of exemption as described below. The IRB, upon review of the application, can determine that the application is not appropriate for the exemption.*

LEVEL OF DETERMINATION CHECKLIST #1 EXEMPT REVIEWS

A study may qualify for an exempt IRB review if it fits into one of the categories outlined below**. Check all those that apply:**

____Category 1: 45 CFR 46.101(b)(1)

Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(a) research on regular & special education instructional strategies, or

(b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

____Category 2: 45 CFR 46.101(b)(2)

FOR ADULTS: Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior UNLESS

(a) data obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects;

(b) any disclosure of the human subjects' responses would place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and/or

(c) the research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

____Category 3: 45 CFR 46.101(b)(3)

FOR SUBJECTS WHO ARE ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE: Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior.

____Category 4: 45 CFR 46.101(b)(4)

Research involving the collection or study of existing data, documents, records, or specimens if:

(a) the sources are publicly available; or

(b) the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers or codes linked to the

subjects. **Note 1**: "Existing" means the data have already been collected for some other purpose at the time the research is proposed.

"Publicly available" means available to the general public, with or without charge. Note: Under condition (b) above, investigators with legitimate access may view identified information, but may not record identities, identifiers, or codes that link private information to individual subjects. Even a brief recording of identifiers or codes disqualifies the exemption. This category excludes studies of publicly authored documentation such as newspaper articles, novels, works of art, or a literature review.

____**Category 5: 45 CFR 46.101(b)(5)**

Research and demonstration projects that are conducted by or subject to the approval of supporting agencies, and which are designed to study, evaluate, or otherwise examine:

(a) public benefit or service programs;
(b) procedures for obtaining benefits or services under those programs;
(c) possible changes in or alternatives to those programs or procedures; or
(d) possible changes in methods or levels of payment for benefits or services under those programs.

____**Category 6: 45 CFR 46.101(b)(6)**

Taste and food quality evaluation and consumer acceptance studies,

(a) if wholesome foods without additives are consumed or
(b) if a food is consumed that contains a food ingredient at or below the level, and for a use, found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration and approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE:

The exempt categories do not apply to research involving deception of subjects, sensitive behavioral research, or to research involving children, pregnant women, military service veterans, prisoners, fetuses, individuals who are decisionally impaired including psychiatric patients, and other subject populations determined to be vulnerable

NOTE: Even if your initial determination is "Exempt", be sure to complete the following checklists for "Expedited" and "Full" reviews. If any of those characteristics apply, your study is not "Exempt".

LEVEL OF DETERMINATION CHECKLIST #2: EXPEDITED REVIEWS

Note: If you determine that your study qualifies for expedited review, complete this checklist and submit a copy with your IRB Application.

Expedited Review by the IRB is provided for research which involves no more than minimal risk, no vulnerable populations, or review of minor changes in previously approved research or research protocols. For the review covered by the regulations 45 CFR 46.110, the IRB will determine that all of the requirements are satisfied.
Minimal risk as defined by 45CFR 46.102(I) http://www.hhs.gov/ohrp/ means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. A study may qualify for an expedited IRB review if it fits into one of the categories outlined below.

Check all those that apply:

____ 1. Studies involving the recording of information so that participants are identifiable (audio or video recordings) require at least an expedited review

____ 2. Studies using instruments, questionnaires, or surveys that have been generated or modified by the researchers require an informed consent and at least an expedited review.

____ 3. Obtaining data from subjects 19 years or older using routine noninvasive procedures

____ 4. Analysis of video or audio recordings

____ 5. Moderate exercise by healthy volunteers

____ 6. Studies involving collection of existing unidentifiable specimens by non-invasive means.

____ 7. Studies of individual or group behavior, or characteristics of individuals, without manipulating subjects' behavior and in a manner that does not cause stress to subjects

NOTE: Even if your initial determination is "Expedited", be sure to complete the checklist for "Full" review. If any of those characteristics apply, your study is not "Expedited".

LEVEL OF DETERMINATION CHECKLIST #3: FULL REVIEWS
Note: If you determine that your study requires full review, complete this checklist and submit a copy with your IRB Application.

A full review is indicated under the following conditions. **Check all those that apply**. If you check even one category, your proposal will require a full IRB review

____ 1. Surveys or interview questions whose answers, if known outside the research, would create legal liability or adverse financial or employment consequences for the participant

____ 2. Surveys of interviews involving questions dealing with very personal and sensitive behavior, such as sexual behavior, alcohol or drug use, or if subjects may be placed at risk for criminal or civil penalties or would otherwise suffer embarrassment or humiliation if the subjects' responses were to become known outside the research.

____ 3. Studies that include members of a *protected population* in the pool of participants, including but not limited to children under age 19, veterans of military service, persons who are decisionally impaired, fetuses, pregnant women, prisoners, and anyone else who cannot provide informed consent

____ 4. Studies involving deception or if the subjects are not fully informed of the purpose and procedures of the study

____ 5. Studies involving support from non-university sources requiring full IRB approval

____ 6. Likelihood of risk or substantial stress or discomfort to the subject

____ 7. Procedures that may potentially threaten or embarrass subjects

____ 8. Personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher

____ 9. Healthcare procedures not conducted for the primary benefit of the subject

____ 10. Diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice

____ 11. Exposure to surgery, drugs, or chemical agents

____ 12. Exposure to electromagnetic radiation (X-rays, microwaves), lasers, high frequency sound waves

____ 13. Collection of blood samples or other body fluids in any amount

NOTE: If there is any doubt of the procedures or participant matter of any Exempt study, an Expedited or Full Review Application should be submitted to the IRB.
NOTE: Studies involving more than minimal risk to participants will not be approved for study at Clarkson College.

(Level of Determination information modified from Belmont University Institution Review Board: http://www.belmont.edu/irb/ , Retrieved 4/04/2011)

Section 5: IRB Guidelines and Application

A. IRB Applications will be reviewed with specific attention to the components in the applications that address the following:

1. Purpose of the study.
2. Description of population.
3. Description of subject selection.
4. Description of study sites.
5. Methods and procedures for data collection.
6. Process and procedures of informed consent.
7. Documentation of informed consent.
8. Compensation for participants.

B. Applications will be critiqued attending to Federal Regulations 45, Part 46, section 111 with particular evaluation of the following:

1. *Risks, physical and mental harms to subjects are minimized*:
   - **(a)** By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   - **(b)** whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. *Risks to subjects are reasonable* in relation to the anticipated benefits (risk/benefit ratio), if any, and the importance of the knowledge that may reasonable be expected to result. Only consider those risks and benefits that may result from the research. Do not consider long- range effects of applying knowledge gained in research (for example, the possible effects of the research on public policy) as among those research risk that fall within the purview of responsibility.
3. *Selection of subjects is equitable*. Take into account the purposes of the research and the setting in which the research will be conducted. Be particularly cognizant of the special problems of research involving vulnerable population, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantage persons.
4. *Informed consent will be sought* from each prospective subject or the subject's legally authorize representative, in accordance with, and to the extent required by §46.116.
5. *Informed consent will be appropriately documented*, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provision for *monitoring the data collected to ensure the safety of subjects*.
7. When appropriate, there are *adequate provisions to protect the privacy of subjects* and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, *additional safeguards* have been included in the study to protect the rights and welfare of these subjects.

Application for Research Approval

Note: Be sure to read Directions for Application (pp. 7-9) and complete your Level of Determination checklist (pp. 13-17**) BEFORE** attempting to complete this form.

Date:
Title of Study (all caps and bold):
Name of Applicant(s):
Phone Number(s) of Applicant(s):
Email Address (es) of Applicants:
CLARKSON COLLEGE Research Advisor or Committee Chair:
Planned Starting Date for Research:
Planned Ending Date for Research:
(Note: IRB approvals are granted for a maximum of one year, although an extension may be requested).

Level of Determination requested: ____ Exempt ____ Expedited ____ Full

1. Brief Explanation for Level of Determination requested. (Be sure to also include the appropriate Level of Determination checklist with this application).

2. Purpose of the Study. Briefly identify the specific aim of the research – why is the research being conducted?

3. Background and Rationale. Provide a summary of the background information and reason(s) this research is needed. State the research question(s). State the hypotheses, if applicable. Overview relevant research that provides a foundation for this study:

a. An exempt review requires at least a one-page overview with at least two relevant citations and a reference page.

b. An expedited review requires a1-2-page overview with at least four relevant citations and a reference page.

c. A full review requires a 1-3 page rationale that should be distilled from the investigator's review of the literature. This should include five or more citations and a reference page. If a grant application or other type of proposal exists, simply summarize the literature and attach the proposal as an appendix to this application. Remember that in-text citations and references must be written in APA style.

4. Number of Participants Expected.
Indicate the minimum and maximum number of participants. If more than one site is used, please indicate the maximum number of participants per site.

5. Characteristics of Participants. What are the specific inclusion criteria for participation? If there are participation restrictions (e.g., gender, race, religion, age, etc.), provide rationale as to why these restrictions are necessary.

6. Method of Participant Recruitment. Describe all techniques used to recruit individual participants and methods used to seek site approval for agencies and locations other than Clarkson College. All recruitment materials including phone scripts, email contents, letters, flyers, etc. must be attached to this application.

7. Study Site(s). Describe specifically where the study will be conducted. You must attach letters of agreement with agencies or locations. This information must be provided as documentation before full approval with be given.

8. Description of Research Design. Describe whether you will be using a quantitative, qualitative, or mixed methods approach. Briefly note how you will ensure validity and reliability in your study. (Note: A poorly-designed study may be considered a waste of research participants' time, so could be considered unethical and will not be approved by the IRB).

9. Description of Procedures. Describe the study. Discuss study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study, if applicable; how data are to be collected (questionnaire, interview, focus group, audio taping, videotaping or other measures). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject, outcome measurements, and follow-up procedures.

10. Confidentiality. Address how data will be kept confidential. Will any identifiers be used to specifically link data to an individual participant? If so, provide justification as to why identification of individuals is necessary. If data will be aggregated, mention that.

11. Informed Consent. (See guidelines in Section 4 for full information).

Describe who will be obtaining consent (or permission) and from whom. Include description, as relevant, of any waiting period between the initial consent discussion and obtaining consent, and steps that will be taken to minimize coercion or undue influence. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child if appropriate. If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). 12
Applicants must include the Informed Consent Form(s) with the application. The form should include full disclosure of the study.

SECTION 6: IRB CONSENT FORM GUIDELINES
DEVELOPMENT OF THE INFORMED CONSENT FORM

The following instructions and examples are provided to assist in development of the Informed Consent Form.

General Formatting Directions:
Consent forms must be printed with CLARKSON COLLEGE letterhead (provided in Appendix D)
All forms should be submitted suitable for reproduction (printed single sided) using a 12 point font (Times New Roman or Ariel are recommended) and one-inch margins. Each page of the consent form should be full without inappropriate divisions; sections can be split so that large blank areas do not exist.
Upon final approval, all pages must include (1) the assigned IRB number in the upper left, (2) the page number in the upper right corner, (3) a participant's initial blank in the lower right corner (see example)

The following should be considered when developing the consent form:
1. **Second Person Language:** The informed consent form must be written in the second person. When combined with conditional language, utilization of the second person personalizes the consent form and reflects the existence of voluntary decision-making on the part of the prospective participant.

2. **Readability:** The consent form must be written in simple enough language so that it is readily understood by the least educated of the participants to be utilized. Normally the highest level of language in the consent form should equate to **a 6th grade** standard depending on the subjects being recruited for the study. Scientific terms and abbreviations should be avoided. Use brief sentences and one syllable words when possible. Utilize the Microsoft program to obtain the Flesch-Kincaid Grade Level and put that information in your application. See references for more information.

3. **Clarifying Consent Form Sections:** The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the prospective participant focus on each individual element of consent thereby increasing the validity of the consent process.

4. **REQUIRED Consent Form Formats are provided on the following pages:** Structure the consent forms just as these are structured. Provide the questions in bold and below the question provide the appropriate statements. Examples of the statements are given in box parentheses. If necessary, alter statements to fit your study, but the statements must include all elements of those provided. Your consent form will probably be only two pages in length.

5. **Under-aged Participants:** Please note that: *adult// participants must be 19-years of age or older in Nebraska.* Each state determines the age of adulthood. If participants are under 19-years of age in Nebraska, different consent forms must be used. See the Adolescent Assent Form and the Parent and Child Consent Forms.

6. **Waiver of Written Consent Documentation**:
Justification for a waiver of written (i.e., signed) consent. The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true:

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). Participants should be asked whether they want documentation linking them with the research, and the participants' wishes will govern whether they sign the form. Note: This justification cannot be used in FDA-regulated research.

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey). Explain.

Applicants who are seeking a Waiver of Informed Consent **MUST** complete a Request for Waiver of Written Consent Documentation (see p. 30). It should be noted that consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated documents.

7. RIGHTS FOR RESEARCH PARTICIPANTS Each participant in your research study needs to receive a hard copy of the following form (or one like it that has been adapted to your population):

THE RIGHTS OF RESEARCH PARTICIPANTS

AS A RESEARCH PARTICIPANT AT Clarkson College YOU HAVE THE RIGHT:

1. TO BE TOLD EVERYTHING YOU NEED TO KNOW ABOUT THE RESEARCH BEFORE YOU ARE ASKED TO DECIDE WHETHER OR NOT TO TAKE PART IN THE RESEARCH STUDY. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

2. TO FREELY DECIDE WHETHER OR NOT TO TAKE PART IN THE RESEARCH.

3. TO DECIDE NOT TO BE IN THE RESEARCH, OR TO STOP PARTICIPATING IN THE RESEARCH AT ANY TIME. This will not affect your relationship with the investigator or Clarkson College.

4. TO ASK QUESTIONS ABOUT THE RESEARCH AT ANY TIME. The investigator will answer your questions honestly and completely.

5. TO KNOW THAT YOUR SAFETY AND WELFARE WILL ALWAYS COME FIRST. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

6. TO PRIVACY AND CONFIDENTIALITY. The investigator will treat information about you carefully and will respect your privacy.

7. TO KEEP ALL THE LEGAL RIGHTS THAT YOU HAVE NOW. You are not giving up any of your legal rights by taking part in this research study.

8. TO BE TREATED WITH DIGNITY AND RESPECT AT ALL TIMES.

THE INSTITUTIONAL REVIEW BOARD IS RESPONSIBLE FOR ASSURING THAT YOUR RIGHTS AND WELFARE ARE PROTECTED. IF YOU HAVE ANY QUESTIONS ABOUT YOUR RIGHTS, CONTACT THE INSTITUTIONAL REVIEW BOARD CHAIR AT.402-552-6093.*

ADAPTED FROM THE UNIVERSITY OF NEBRASKA MEDICAL CENTER, IRB WITH PERMISSION.

CLARKSON COLLEGE CONSENT FORMS
ADULT CONSENT FORM
IRB#: Approval Date: Expiration Date:

Title of this Research Study. List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.

Invitation. Invite the prospective participant to participate in the study using the following standard invitation to participate: *You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.*

Why are you being asked to be in this research study? Explain succinctly and simply why the prospective participant is eligible to participate. As appropriate, major eligibility criteria may be included in this section (e.g. "You are being asked to be in this study because you are either an employee or a supervisor working a night shift").

What is the reason for doing this research study? This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential participant understand why the research is being done (e.g., "People who work at night employ different strategies for staying awake during their shifts. These methods are likely to be different between employees and supervisors, because of their different levels of responsibility. This research is designed to (1) better understand these strategies and (2) determine whether „supervisor strategies" could be successfully used by employees.") This information should be provided in simple language without reference to the participant.

What will be done during this research study?
Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability. The description should include when the research activities will take place, where they will occur and how much time will be required. If it is important for the participants to know prior to consenting that the study involves randomization, explain that they will be assigned by chance to a study group. Explain the study groups. Indicate if there are specific requirements of the research participants, such as follow-up interviews or questionnaires.

What are the possible risks of being in this research study? The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress. Alternately, if there are no known risks use this standard clause:
[There are no known risks to you from being in this research study.]

What are the possible benefits to you? If direct participant benefits can reasonably be anticipated as a result of participating in the protocol, then describe these possible benefits. Conclude with the following standard clause:
[However, you may not get any direct benefit from being in this research study.]
If direct participant benefits are NOT anticipated, then use the following standard clause:
[You are not expected to get any direct benefit from being in this research study.]

What are the possible benefits to other people? State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective participants' position.

What are the alternatives to being in this research study? Describe, in reasonable detail, alternatives the prospective participant may have available. Alternately, use the following standard clause if applicable:
[Instead of being in this research study you can choose not to participate.]

What will be in this research study cost you?
This section should state the financial obligations the participant will incur as a result of participating in the study. If there are no financial obligations to the participant then use the following standard clause:
[There is no cost to you to be in this research study.])

Will you be paid for being in this research study? If the participant will receive compensation for participating in the research, state the amount of compensation and conditions for payment. If no compensation is provided, then use the following standard clause:
[You will not be paid or compensated for being in this research study.]

What should you do if you have a problem during this research study? Your estimation of risk determines what additional information you will include in this section.

For studies classified as minimal risk, use the following standard clause:
[Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.]

Note: Clarkson College will not approve studies that have greater than minimal risk to participants

How will information about you be protected? Begin with the following standard clause:
[Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.]
Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective participant, follow the introductory standard clause (above)

with a brief description of the precautions which will be utilized to protect that data. Finally, for all protocols, conclude with the following standard clause:
[The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.]

What are your rights as a research participant? Use the following standard clause:
[You have rights as a research participant. These rights have been explained in this consent form and in The Rights of Research Participants that you have been given. If you have any questions concerning your rights, talk to the investigator or call the Clarkson College Institutional Review Board (IRB), telephone (402)-552-6093.]

What will happen if you decide not to be in this research study or decide to stop participating once you start? Use the following standard clauses:
[You can decide not to be in this research study, or you can stop being in this research study (—withdraw‖) at any time before, during, or after the research begins. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator, or with Clarkson College (also add any other sites to this statement, if needed. You will not lose any benefits to which you are entitled.
If the research team gets any new information during this research study that may affect whether you would want to continue being in the study, you will be informed promptly.]

Documentation of informed consent. Use the following standard clause:
[You are freely making a decision whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study. If you have any questions during the study, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep. If you are 19 years of age or older and agree with the above, please sign below.]

_____ _____
Signature of Participant: Date: Time:

Participant Initials _____ **(**Put place for participant initials on each page.)
For all studies include the following investigator certification clause: [
[My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.]

Signature of Investigator:
Date:

Authorized Study Personnel. Identify all personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Principal Investigator, Secondary Investigator(s), and Participating Personnel. Include day phone numbers and e-mails for all listed individuals.
Principal Investigator: _____ Phone: _____
Secondary Investigator: _____ Phone: _____

Participant Initials _____ should be at bottom of each page to signify they have read each page.

PARENT AND CHILD PERMISSION FORM
IRB#: Approval Date: Expiration Date:

Title of this Research Study. List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.
Invitation. Invite the parent or guardian to decide whether or not to give permission for their child to participate in the study using the following standard invitation to participate:
[Your child is invited to take part in this research study. The information in this form is meant to assist you in the decision of whether or not to give permission for them to take part. If you have any questions, please ask.]

Why are you being asked to be in this research study? Explain succinctly and simplistically why the prospective participant is eligible to participate. As appropriate, major eligibility criteria may be included in this section (e.g. "Your child is being asked to be in this study because she or he participates in aquatic therapy").

What is the reason for doing this research study? This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential participant understand why the research is being done (e.g.,.") This information should be provided in simplistic language without reference to the participant.

What will be done during this research study? Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability.
The description should include when the research activities will take place, where they will occur and how much time will be required. If it is important for the participants to know prior to consenting that the study involves randomization, explain that they will be assigned by chance to a study group. Explain the study groups. Indicate if there are specific requirements of the research participants, such as follow-up interviews or questionnaires.

What are the possible risks of being in this research study? The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress. Alternately, if there are no known risks use this standard clause:
[There are no known risks to your child from being in this research study.]

What are the possible benefits to you? If direct participant benefits can reasonably be anticipated as a result of participating in the protocol, then describe these possible benefits. Conclude with the following standard clause:
(However, your child may not get any direct benefit from being in this research study.)
If direct participant benefits are NOT anticipated, then use the following standard clause:
[Your child is not expected to get any direct benefit from being in this research study.]

What are the possible benefits to other people? State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective participants' position.

What are the alternatives to being in this research study? Describe, in reasonable detail, alternatives the prospective participant may have available. Alternately, use the following standard clause if applicable:
[Instead of being in this research study you can choose for your child not to participate.]

What will being in this research study cost you? This section should state the financial obligations the participant will incur as a result of participating in the study. If there are no financial obligations to the participant then use the following standard clause:
[There is no cost to you or your child to be in this research study.]

Will you be paid for being in this research study? If the participant will receive compensation for participating in the research, state the amount of compensation and conditions for payment. If no compensation is provided, then use the following standard clause:
[You or your child will not be paid or compensated for being in this research study.]

What should you do if you have a problem during this research study?
Your estimation of risk determines what additional information you will include in this section. For studies classified as minimal risk, use the following standard clause:
[Your welfare and your child's welfare are the major concern of every member of the research team. If you or your child has a problem as a direct result of being in this study, you or your child should immediately contact one of the people listed at the end of this consent form.]
Note: Clarkson College will not approve research that is greater than minimal risk.

How will information about you be protected?
Begin with the following standard clause:
[Reasonable steps will be taken to protect your privacy, your child's privacy and the confidentiality of all study data.]
Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective participant, follow the introductory standard clause (above) with a brief description of the precautions which will be utilized to protect that data. Finally, for all protocols, conclude with the following standard clause:
[The only persons who will have access to your or your child's research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study may be published in scientific journals or presented at scientific meetings but your identity and your child's identity will be kept strictly confidential.])

What are your rights as a research participant? Use the following standard clause:
[Your child has rights as a research participant. These rights have been explained in this consent form and in The Rights of Research Participants that you have been given. If you have

any questions concerning your rights or your child's rights, talk to the investigator or call the Institutional Review Board (IRB), telephone (402)-399-2400.]

What will happen if you decide not to be in this research study or decide to stop participating once you start? Use the following standard clause:
[You can decide for your child not to be in this research study, or you and/or your child can decide to stop being in this research study (—withdraw‖) at any time before, during, or after the research begins. Deciding not to be in this research study or deciding to withdraw will not affect your relationship or your child's relationship with the investigator, or with Clarkson College (also add any other sites to this statement, if needed).
Your child will not lose any benefits to which she or he is entitled.
If the research team gets any new information during this research study that may affect whether you want your child to continue being in the study, you will be informed promptly.]

Documentation of informed consent. Use the following standard clause for the remainder for this page:
[You are freely making a decision whether to allow your child to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to give permission for your child to be in the research study. If you or your child has any questions during the study, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Parent: _____ Date: Time: _____
Signature of Participant:_____ Date: Time:_____

For all studies include the following investigator certification clause:
(My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant and parent. In my judgment, the parent possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.)
Signature of Investigator: _____Date: _____

Authorized Study Personnel
Identify all personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Principal Investigator, Secondary Investigator(s), and Participating Personnel. Include day phone numbers for all listed individuals.

Principal Investigator _____ Phone_____
Secondary Investigator _____Phone _____
Participating Personnel _____Phone

_____ Parent Initials _____ Child Initials _____ (initials of both should be at bottom of each page to signify they have read each page)

ADOLESCENT ASSENT FORM FOR PARTICIPANTS AGED 12 to18 years
(use both Adolescent Assent form and Parent Consent form for 12 to 18 year olds.
IRB#: Approval Date: Expiration Date:

Title of this Research Study. List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.

Invitation. Invite the prospective participant to participate in the study using the following standard invitation to participate. Be sensitive to readability levels:
{We're asking you to be in a research study. As you know, research is a way to learn new things. You will only be in the study if you decide that you want to be. We'll tell you about the study and then you should take time to make your decision. You should talk to your parents or guardian before you decide. }

Why are you being asked to be in this research study? Explain simply why the prospective participant is eligible to participate. As appropriate, major eligibility criteria may be included in this section (e.g. "You are being asked to be in this study because you are a girl between the ages of 12 and 18").

What is the reason for doing this research study? This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential participant understand why the research is being done.
For example: "This study will look at what girls your age think about leadership".

What will be done during this research study? Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability. The description should include when the research activities will take place, where they will occur and how much time will be required. For example: "First you will be given a questionnaire with 40 statements. Then you will be asked to read each item and give it a score from 1-5, depending on how much you agree or disagree with it."

What will being in this research study cost you?
This section should state the financial obligations the participant will incur as a result of participating in the study. If there are no financial obligations to the participant then use the following standard clause:
[There is no cost to you to be in this research study.]

Will you be paid to be in this research study?
This section should state any financial arrangements made to remunerate the participant as a result of participating in the study. If there is no remuneration, then use the following standard clause:
[You will not be paid to be in this research study.]

What are the possible good things about being in this study? Explain the benefits. If direct participant benefits can reasonably be anticipated as a result of participating in the protocol, then describe these possible benefits. Conclude with the following standard clause:
[However, there might not be any particular good things about being in this research study.]

What are the possible bad things about being in this study? The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress. Alternately, if there are no known risks use this standard clause:
[We don't think there are any bad things about being in this research study.]

How long will this take? Explain the time commitment. Example: "Most students need 30-45 minutes to finish this questionnaire. **Will people know that I am in the study?** Describe confidentiality. Avoid using the word "secret". Example: The other girls in your Girl Scout Troop will know that you are in the study. The Researchers will also know that you are in the study, but they won't use your name if they talk or write about it.

Is it O.K. to say "No, I don't want to be in this study"?
[Yes. Instead of being in this research study you can choose not to participate. If you decide to be in the study and then change your mind, you can stop being in the study at any time. No one will be mad or upset.]

Is there anything else I should know about the study? If there is additional information that needs to be disclosed, use this section.

What are your rights as a research participant? Use the following standard clause:
[You have rights as a research participant. These rights have been explained in this form and in The Rights of Research Participants that you have been given. If you have any questions concerning your rights, talk to the investigator or call the Institutional Review Board (IRB) at Clarkson College, 402-552-6093.]

Do you understand and do you want to be in the study?
I understand. All my questions were answered. Please check one:
___I want to be in the study
___I don't want to be in the study

_____ _____
Your signature Today's date

_____ _____
Signature of person explaining the study Today's date

Participant Initials _____ **(**must be at bottom of each page of consent form to signify they have read each page.)

ELECTRONIC CONSENT FORMS

In limited instances where research is being conducted utilizing an online survey or when consent is being sought for a scheduled phone interview, an alternative to the standard Informed Consent Form format can be used. The applicant must carefully explain the rationale for use of this alternative form in the IRB application form.

This format contains all of the required components of the standard format, but uses an assumed consent. Consent is assumed when participants choose to complete an online survey or when they agree to participate in a scheduled phone interview when contacted.

With survey research, participants can choose not to participate through not completing the survey or to end their participation and not complete the survey instrument at any time. A statement addressing this option is required in the Online Consent Form format.

With phone interviews, participants can choose not to schedule a phone interview when contacted or can end their participation at any time during the interview. At the beginning of the interview and periodically throughout the interview, it is important that researchers acknowledge the participant's right to end the interview at any time.

The template for Media Consent Forms is provided. It includes the required elements and gives IRB applicants the opportunity to put in information relevant to their study's purposes and procedures.

The Rights of Research Participants document must be provided as part of the Online Consent Form**. All online surveys must be distributed through the Office of Assessment and Evaluation at Clarkson College**. Online data will be stored in that office also.(See below for instructions and required format).

Template for Electronic Consent

Date: **(TITLE OF STUDY) – ALL CAPITALIZED LETTERS AND BOLD TYPE IRB #** (enter IRB number assigned) Dear _____**,** (Address according to the role or connection that makes them eligible for invitation to participate. For example, —Dear Nursing Educator||).

You are invited to take part in a research study because you are (note characteristic that make the person eligible). The purpose of this study is to (describe the general purpose or intention of the study). This research study is being conducted as part of the requirements of my (state type of degree program) program at Clarkson College. You may receive no direct benefit from participating in this study (use the previous statement unless you expect the participant to receive a direct benefit**),** but the information gained will be helpful to (describe what the expected benefits of knowledge or understanding gained to either the research community or public at large).

Should you decide to participate you are being asked to complete the following on-line survey which should take approximately (identify specific amount of time) to complete. Your participation is strictly voluntary. Furthermore, your response or decision not to respond will not affect your relationship with Clarkson College or any other entity. Please note that your

responses will be used for research purposes only and will be strictly confidential. No one at Clarkson College will ever associate your individual responses with your name or email address. The aggregate information from this study may be published in journals and presented at professional meetings.

Your completion and submission of the questionnaire indicate your consent to participate in the study. You may withdraw at any time by exiting the survey. This study does not cost the participant in any way, except the time spent completing the survey. There is no compensation or known risk associated with participation. Please read The Rights of Research Participants below. If you have questions about your rights as a research participant, you may contact the Clarkson College IRB Board at 402-552-6093.. Thank you sincerely for participating in this important research study. If you have comments, problems or questions about the survey, please contact the researcher(s).

If you are 19 years of age or older and agree to the above please proceed to (put in link to survey) and begin the survey.

Sincerely,

Principal Investigator(s)'s name(s) Principal Investigator(s)'s Contact Information
Secondary Investigator(s)'s name(s) Secondary Investigator(s)'s Contact Information

Request for Waiver of Written Consent Documentation

Under special circumstances, investigators may request a waiver to obtain written informed consent from research subjects. This type of waiver will be given only when there are compelling reasons to do so.

Applicants who are seeking a Waiver of Informed Consent MUST complete a Request for Waiver of Informed Consent. It should be noted that consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated document.

Clarkson College Waiver of Written Consent Documentation:

Justification for a waiver of written (i.e. signed) consent. The requirement for written consent may be waived by the IRB if either of the following is true:

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). *Participants should be asked whether they want documentation linking them with the research, and the participants "wishes will govern whether they sign the form.* Note: This justification cannot be used in FDA-regulated research.

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey).

In order for your request to be considered, please answer fully each of the following questions. Make sure that each response includes thorough explanation and description. Please provide supporting documentation, as appropriate.

1) **Title of Study: (All caps, bold face)**

2) Will waiving the written informed consent adversely affect subjects, their rights, or their welfare? Please explain.

3) Will pertinent information be provided to the subjects later, if appropriate? If yes, when?

4) Is there an adequate plan to protect the identifiers from improper use and disclosure?

Briefly, explain the plan.
Principal Investigator _____ Date _____

SECTION 7: RECRUITMENT MATERIALS GUIDELINES

General Recruitment

Advertisements and recruitment material are considered an extension of the informed consent and participant selection process. As such, recruitment of participants into a study may not begin prior to IRB approval. The IRB must approve all recruitment methods and material (flyers, letters, brochures, e-mail advertisements, radio announcements, etc.) prior to use.

Materials must also be submitted for review and re-approval at the time of continuing review. The content of recruitment materials and the method for communicating it cannot create undue influence or contain misleading or exculpatory language. The following are examples of common recruitment methods for human research studies. All recruitment methods must be described in the IRB application.

- Use advertisements, notices, and/or media to recruit subjects. Examples include flyers posted in public settings, newspaper ads, and radio and television advertisements.
- Direct recruitment of participants who are unknown to the researchers. Examples include random digit dialing, approaching people in public settings, snowball sampling, and use of social networks.
- Provide colleagues with an IRB-approved Introduction letter describing the study. This letter would explain the purpose and procedures of the study and inform individuals how to contact the research team. Researchers are prohibited from having access to participant/patient names, addresses, or phone numbers; interested individuals must initiate contact.
- Send an IRB-approved letter to certain individuals asking for referrals of eligible participants interested in the study. The researchers may provide the referring individual with IRB-approved recruitment material for the study to give to potential participants. If interested, the participant contacts the researchers for additional information.
- Avoid approaching your own students or employees. This method raises ethical concerns because individuals may have difficulty saying "no" to an authority figure.

Advertisements

Advertisements should contain information that provides enough detail to allow the prospective participant to determine his/her eligibility and interest. Visual effects that may create undue influence cannot be used, for example, placing the phrase "GET PAID $100!!!" in all capital letters or an extra-large font while the rest of the ad is in lower case or a smaller font is not acceptable.

Generally, the elements of any advertisement to recruit participants should be limited to the following:

- The name of the Principal Investigator(s) and Clarkson College affiliation;
- An accurate description of the condition(s) under study and/or the research purpose, e.g., "low fat vs. low carb diets for weight loss," or "acculturation of Cuban immigrants;"

- In summary form, the key eligibility criteria that will be used to admit (or exclude) participants into the study, e.g., an acceptable age range or unacceptable physical limitations; straightforward and truthful descriptions of the benefits, if any, to the participant from participating in the study, e.g., "free health screening;"
- If applicable, a statement that compensation is available or a statement of how much compensation is available, e.g., "Participants may receive up to $100;" the amount / length of time or other commitment required of the participants; the location of the research and contact information for obtaining additional information.

Advertisements must display the IRB validation stamp, unless an exception has been granted by the IRB. If it is not feasible to make copies of the validated version, it is acceptable to use the exact wording of the validation stamp: "Clarkson College IRB, Approval On (date), Approved until (date), Approved by (initials)."
Advertisements **cannot** incorporate elements that:

- Do not state or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form;
- Do Not Use catchy words like "free" or "exciting."

Recruitment/Advertising Tips and Suggestions

- Understand the target population. What media does the population read or view? Where do they go for information?
- Make concerted efforts to recruit participants from minority and under-represented groups. Describe those efforts in the IRB application.
- Spend the time to make the recruitment flyers easy to read and understand. Triple-check for typos, as your work will reflect directly on Clarkson College. Advertisements must be written using lay language, at an 8th grade reading level (similar to the level used by popular magazines and newspapers) that is appropriate for the participant population. You should select a font style and size that is easy to read such as Times Roman, Arial, or Garamond.

(Modified from University of Connecticut IRB Guidance for Advertising and Recruitment, http://irb.uconn.edu/adv_guidance.html

SECTION 8: APPLICATION FOR EXTENSION OR CHANGE OF PROTOCOL

Procedures for Requesting Extension or Change of Protocol Applicants may request approval to make changes (amendments) in various aspects of a project. All changes must be approved by the IRB prior to implementation. Amendments include: changes in experimental design, insertion of new information, correction of errors in text, change in primary investigator, change in study duration, change in numbers of subjects, changes in inclusion or exclusion criteria, or number of locations (site). A written request must be submitted. If the changes of protocol requested will require changes in the description of procedures in the application, recruitment materials, or in the Informed Consent, attach the revised documents to the Extension or Change of Protocol Form with changes tracked or highlighted as well as a clean copy. Upon completion of review of the application, the primary investigator(s) will be notified of either a request for additional information or an approval notification.

CLARKSON COLLEGE INSTITIUTIONAL REVIEW BOARD

EXTENSION OF STUDY FORM:

In the event that a researcher is unable to collect the data in the one calendar year time frame or needs to change the protocol for data collection, a researcher may request to the IRB an extension of time to collect data or a change of protocol. The IRB will consider the request and determine whether further approval will be granted.

Date Extension Request is being submitted:

IRB Number:

Primary Investigator:

Primary investigator's phone number:

Primary investigator's email address:

Degree being pursued (if applicable):

Advisor's name (if applicable): Department:

Title of Research Proposal:

Expected time needed to complete the project:

Rationale for the request:

Signature of Requestor_____

If student, Signature of Faculty Advisor_____

CHANGE OF PROTOCOL:

Investigators may request approval to make changes (amendments) in various aspects of a project. All changes must be approved by the IRB prior to implementation. Amendments include: changes in experimental design, insertion of new information, correction of errors in text, change in primary investigator, change in study duration, change in numbers of subjects, or number of locations (site), slight changes in population sample composition. A written request must be submitted. Upon completion of review (generally within 1 week of the submission), an approval notification will be sent to the primary investigator.

Date Change of Protocol Request Form is being submitted:

IRB Number:

Primary Investigator:

Primary investigator's phone number:

Primary investigator's email address:

Advisor's name (if applicable):

Department: Degree being pursued (if applicable):

Title of Research Proposal:

Proposed Changes:

Rationale for Proposed Changes: Do these changes affect either the risks or the benefits of this study? Yes No

If yes, please explain:

Note: If the proposed changes require a change to the consent form, submit the new consent form with all changes highlighted.

SECTION 9: CLOSING THE RESEARCH PROJECT

This form is to be completed for all studies approved via expedited or full review procedures. The form must be submitted within 30 days of the conclusion of research activities. The Closing the Study form below should be completed and sent directly to: IRB@ClarksonCollege.edu.

Closing the Study Form Congratulations on completion of your study!
This form is to be completed for all studies approved via expedited or full IRB review procedures. It must be submitted within 30 days of the submission of your article, project, thesis, or dissertation for formal review by faculty or a professional journal publication review board or presentation at a conference. Submit it electronically to: irb@clarksoncollege.edu

Date:

Project Title*:*

Final outcome *(Submitted as a class project, completed as: an undergraduate capstone project, master's thesis, doctoral dissertation, conference presentation, academic article for submission to professional journal—please specify):*

IRB Protocol #:

Initial IRB Approval Date:

IRB Reapproval Date(s):

Please briefly describe the purpose of your research:

Please briefly describe your findings *(or include a copy of your abstract):*

Were any unanticipated problems encountered during your research process? Please explain how they were addressed:

What advice do you have for future Clarkson College researchers?

Investigator's Name(s):

U.S. Mailing Address:

Phone:

CLARKSON COLLEGE Email:

Alternate Email

Section 10: Faculty Review and Approval Form

When a student is the researcher, they must have a Faculty member review and complete this approval form to be submitted with the IRB application.

Student's Name:
Expected Starting Date of Research:
Degree Sought:
Research Title:

Level of Determination: ____Exempt Review ____ Expedited Review ____Full Review

As research advisor, I have reviewed my student's IRB Application. I find that (check):
__ All required components are present in the following order—in a single document with page numbers (See Directions, Section 2):
a. __ Application – APA Style
b. __ References – APA Style
c. __ Level of Determination checklist (appropriate one for your study)
d. __ Consent form(s) on CLARKSON COLLEGE letterhead or waiver of informed consent
e. __ Rights of Research Participants form(s)
f. __ Recruitment materials-flyers, email invitations, letters, etc. (Section 5)
g. __ All data collection instruments (surveys, interview protocols, etc.)
h. __ Ethics certificate (See Section 7)
i. __ Faculty Review and Approval form

I agree that:
__ The research design conforms with discipline standards
__ The student is requesting the appropriate review for her/his research
__ The format of the IRB proposal is accordance with the CLARKSON COLLEGE Application Guidebook.
__ There are no substantial misspellings or other APA style errors that mar the work
__ The research project to be submitted to the IRB has my full support.

Signed _____Research Advisor Date _____
Signed (Do not type; please use electronic signature or sign a hard copy and scan so this can be sent electronically):

Section 11: Instructions for Completing the UNMC IRB Application for Clarkson College IRB Committee Approval. (When using The Nebraska Medical Center as a research site)

Please read and follow these instructions carefully.
PLEASE, DO NOT SUBMIT THE ONLINE APPLICATION TO THE UNMC IRB UNTIL APPROVAL BY THE CLARKSON COLLEGE IRB COMMITTEE IS COMPLETED. Please direct questions regarding the process to Clarkson College IRB Chair: Dr. Linda E. Jensen at jensenlinda@clarksoncollege.edu

1. Completion of CITI Training and certification online at http://www.citiprogram.org is required **before** the IRB application is submitted. See Instructions for completing the CITI training.

2. Next, the researcher/student should view the online video that explains the TNMC IRB Application online procedure using this link: http://www.unmc.edu/irb/
   Print and refer to the **Quick Start Instructions** available

3. Following completion of the video, the student should access the online IRB Application process using the link: https://net.unmc.edu/rss and following the instructions below:

Instructions for Faculty and Students who are The Nebraska Medical Center or Clarkson College Employees and Collecting Data at TNMC

1. If the Faculty member or student is currently a TNMC employee or Faculty at Clarkson College, the assigned Lawson Center (NHS Olympus) ID and Password will allow access to the system. Type the assigned ID and current password into the blanks and check the box entitled: @nebraskamed.com

2. When the student begins the process of the first part of the IRB Application, the student should type their name on the form as the Principal Investigator and the Faculty Advisor's name as the Faculty Advisor.

3. Please remember to **save** the information **FREQUENTLY** when completing the Application.

4. When the Application is completed, save the form as a pdf file. file and forward the file to the Faculty Advisor for approval. The Application Form must be approved by the Faculty Advisor **PRIOR** to submitting the Application to the Clarkson College IRB Committee.

5. Following faculty advisor approval, the pdf file. file should be forwarded to the chairperson of the Clarkson College IRB Committee by e-mail to irb@clarksoncollege.edu

6. The IRB Chair will review the application for its completeness and may provide comments for additional revisions needed prior to acceptance of the IRB Application draft. Following needed revisions, the completed application will be forwarded to each member of the IRB Committee for review and approval. Please be aware that further revisions may be required prior to approval based on all Committee members' review.

SECTION 12: REFERENCES

Belmont University Institutional Review Board. Retrieved (2011. April 4) From Http://Www.Belmont.Edu/Irb/Directions.Html. *Code of Federal Regulations*. Retrieved (2012, July 15) From http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

College Of St. Mary IRB (2010). Application Guidebook. Retrieved (2012, July 15) From https://my.csm.edu/communities/IRB/default.aspx

United States Office of Health and Human Services Office for Human Research Protection, Retrieved (2012, July 15)From http://www.hhs.gov/ohrp

University Of Connecticut IRB Guidance For Advertising And Recruitment. Retrieved (2012, July 15) From http://irb.uconn.edu/adv_guidance.html

University Of Nebraska Medical Center IRB. Retrieved (2012, July 15,) http://www.unmc.edu/irb/